K063218

DEC 14 2006

510(k) Summary of Safety and Effectiveness

510(k) Submitter:

Streck
7002 South 109th Street
Omaha, NE 68128

Official Correspondent:

Carol Thompson
Quality Assurance Manager
(402) 537-5313

Date Prepared:

December 5, 2006

Names of Device:

Trade Name:	*e*-CHECK (XE)™
Common Name:	Assayed hematology control
Classification Name:	Hematology quality control mixture (§ 864.8625)

Predicate Devices:

e-CHECK manufactured by Streck

Description:

e-CHECK (XE) is a suspension of stabilized human and animal blood packaged in glass vials, containing 4.6 mL volumes. Closures are injection molded polypropylene screw top caps. The device will consist of three levels: Low CBC/High Retic (Low Level), Normal CBC/Intermediate Retic (Normal Level), and High CBC/Low Retic (High Level).The vials are packaged in a welled vacuum formed clam-shell container with the package insert and assay sheet.

Intended Use:

e-CHECK (XE)™ is intended to be used as a control for complete blood cell count (CBC), white blood cell differential, reticulocyte and nucleated red blood cell (NRBC) parameters on Sysmex XE – series instruments.

Comparison with Predicate Devices:

Like *e*-CHECK, *e*-CHECK (XE) is intended to enable the user to verify satisfactory performance of Sysmex XE Series hematology instruments in recovery of CBC and white cell differential parameters on whole blood specimens. Both devices contain stabilized human red blood cells, human white cells, and simulated platelets, which properly mimic human whole blood components on Sysmex analyzers.

Unlike e-CHECK, *e*-CHECK (XE) contains simulated human nucleated red blood cells (NRBCs). This allows the user to verify proper performance of NRBCs on the Sysmex XE – 2100. The addition to NRBC is the difference between the two products.

Discussion of Tests and Test Results:

Three studies of *e*-CHECK (XE) were conducted:
I) Lot to Lot Reproducibility and Comparison to Whole Blood; II) Long Term Stability; and III) Open Vial Stability. Study results showed *e*-CHECK (XE) to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating.

Conclusions Drawn From Tests:

Study results show *e*-CHECK (XE) to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating. *e*-CHECK (XE) is a safe and effective product, which fulfills its intended use when used as instructed in the product package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

STRECK
C/O Kerrie Oetter
7002 South 109th Street
Omaha, NE 68128

DEC 14 2006

Re: k063218
Trade/Device Name: e-CHECK
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK
Dated: December 5, 2006
Received: December 6, 2006

Dear Ms. Oetter:
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC

HFZ-404 510(k) Staff
HFZ- 440 Division
D.O.

510(k) Number (if known): K063218

Device Name: e-CHECK (XE)™

Indications For Use:

e-CHECK (XE)™ is intended to be used as a control for complete blood cell count (CBC), white blood cell differential, reticulocyte and nucleated red blood cell (NRBC) parameters on Sysmex XE – series instruments.

Prescription Use__X __ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K063218